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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,185	03/16/2004	Gamer T. Haupt JR.	0838.1002-003	5106
21005 7590 01/09/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

7#

Office Action Summary	Application No. 10/803,185	Applicant(s) HAUPERT, GARNER T.	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event; however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 20-31 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I and Rb^{+} uptake in liposome as the species (claims 1-19 and 32) in the Response to Restriction Requirement filed on October 23, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 20-31 and 33-37 are withdrawn from consideration, and claims 1-19 and 32 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-19 and 32 are indefinite because of the use of the term "HIF". The cited term renders the claim indefinite, it is not clear what the term means. A fully spelled out word should be indicated in the first occurrence. Claims 2-19 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.
4. Claims 12-14 is indefinite because of the use of the term "is derived from". The cited term renders the claim indefinite, it is not clear how different the target cell obtained from a patient is from the original cell in the patient. Use of the term "is obtained from" is suggested.

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Claims 13-14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4, 5, 8-10, 15, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anner *et al.* (Am. J. Physiol. 258, F144-153 (1990)) in view of Hauptert, Jr. (The Sodium Pump, Steinkopff & Darmstadt (pub), N.Y. pp732-742 (1994)).

Anner *et al.* teach inhibition of $\text{Na}^+\text{-K}^+\text{-ATPase}$ by hypothalamic inhibitory factor (HIF) using a miniaturized, two-sided test system containing ATP-filled liposomes having dispersed, randomly oriented renal $\text{Na}^+\text{-K}^+\text{-ATPase}$ molecules and the inhibition was monitored by the uptake of $^{86}\text{Rb}^+$ -containing liposomes, which are separated by Sephadex G-50 column (page F146-F147; Fig.1; claims 4-5, 8), the HIF is isolated from bovine hypothalamus (page F145, right column; claim 19), and the inhibition of inside-out-oriented $\text{Na}^+\text{-K}^+\text{-ATPase}$ (ISO) by other compounds such as digoxin has also been shown (F149; Fig. 3; Table 1; page F149; claims 1). However, Anner *et al.* do not teach monitoring the inhibition of the ouabain-resistant $\text{Na}^+\text{-K}^+\text{-ATPase}$.

Hauptert, Jr. teaches in search of endogenous inhibitor of $\text{Na}^+\text{-K}^+\text{-ATPase}$, it is found that HIF inhibition on $\text{Na}^+\text{-K}^+\text{-ATPase}$ incorporated into liposomes is reversible, which can be monitored by the assay system of Anner *et al.*, and the inhibitions of HIF and Ouabain on

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isoenzymes of the Na^+/K^+ -ATPase and Ouabain-resistant Na^+/K^+ -ATPase are compared, where the existence of isoforms showing different sensitivities to ouabain and HIF, and the Ouabain-resistant α_1 isoform is obtained from rat kidney (pages 733-735; claims 9, 10, 15, 16).

At the time of invention was made, it would have been obvious to one of ordinary skill in the art to combine the two references to screen a compound for HIF inhibitory activity of Ouabain-resistant Na^+/K^+ -ATPase as indicated by Hauptert, Jr. using the assay system indicated by Anner *et al.* because using Ouabain-resistant Na^+/K^+ -ATPase in the assay can provide a method to identify an inhibitor that has target organ selectivity, which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

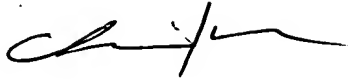
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Chih-Min Kam, Ph. D.

Primary Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min Kam', with a stylized flourish at the end.

CHIH-MIN KAM
PRIMARY EXAMINER

CMK

January 5, 2007